



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/387,135	08/31/99	COSFORD	N SIBIA1290

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HM22/0810

EXAMINER

CHOI, F

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/387,135

Applicant(s)

COSFORD ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the examples which exhibit activity on the hmGluR5a receptor and/or analgesic activity at the specified doses in rats, does not reasonably provide enablement for the other compounds, the modulation of all amino acid receptors, the treatment of the disease conditions or prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record set forth in the prior Office Action and the further reasons below.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that one of ordinary skill in the art would not be required to do undue experimentation. However, it well known in the art that a given compound, at a given concentration will either inhibit or stimulate receptor activity but it cannot both inhibit and stimulate a given receptor at the given concentration. Further, it is well known in the art that disease states may be effected by either inhibiting or stimulating receptor activity. Applicant's own examples show that the compounds falling within the scope of the general formula have different effects on receptor activity (Specification, Pg. 42, Table 1). Applicant has not shown other than what has been specifically tested, what effects a given compound will have on a given

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receptor, i.e. no effect, inhibition or stimulation, whether the effect is concentration dependent, and whether a given disease state will be prevented or treated by inhibition or stimulation of the amino acid receptors. As such, in light of the above and for the reasons of record, a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardon et al. (U.S. Pat. 5,574,036) or Bernardon et al. (U.S. Pat. 6,150,413).

Bernardon et al. (U.S. Pat. 5,574,036) teach adamantyl-substituted polycyclic acetylene compound and salt thereof and a methods of treating and preventing various diseases, such as skin diseases, cancer, inflammatory conditions, viral, immunological conditions and cardiovascular conditions (Column 4, lines 30-36, Column 6, lines 65-68, Columns 7, 8, Claims 1, 6, 8, 23, 25, 32, 34).

Bernardon et al. (U.S. Pat. 6,150,413) teach 5-[4-(4'-Methylbiphenyl-2-yl)but-3-en-(E)-1-ynyl]-thiophene-3-carboxylic acid and 5-[4-(4'-Methylbiphenyl-2-yl)buta-1,3-diynyl]-thiophene-3-carboxylic acid salts thereof and a methods of treating and preventing various diseases, such as skin diseases, cancer, inflammatory conditions, viral, immunological conditions and cardiovascular conditions (Column 4, lines 21-34, Column 7, lines 14-16, 34-36, Column 9, lines 65-68, Columns 10, 11, Column 12, lines 1-50, Claims 1, 5, 6, 8, 19, 20, 23, 30-46).

The difference between the cited reference and the claimed invention is that the claimed reference does not expressly disclose a method of treating or preventing diseases or salts of the claimed compounds. However, the cited reference amply suggests the same as compounds falling with the scope of the claims are taught and methods of treating or preventing various disease states are taught and pharmaceutically acceptable salts are well known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any of a number of salts, including salts falling with the scope of the claimed invention, with the expectation that they would be pharmaceutically acceptable and that the compounds would be effective in treating the various disease states.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

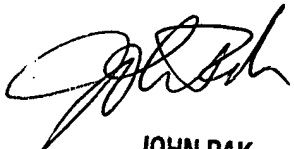
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

August 8, 2001

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

